MEMORANDUM

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cc: Brad Estes
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From: Larry Boyd LB

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Subject: **NOTES ON THREADED DOWEL CONCEPTS OF DR. MICHELSON**

Following for your review and information are some of my notes and comments on the Michelson technology. These are based on my review of information prior to our meeting and contain some of the answers to my various questions, which were answered by Dr. Michelson on Tuesday. The notes refer to some terminology used by Dr. Michelson and found in the patent application. Let me know if you have any questions or comments.

I. Various Features and Benefits

1. Instrumentation is guarded to protect against tissue contact and contact with the neurovascular structures. Instrumentation also features drill stops to prevent over drilling. No external retractors (e.g., lamina spreaders) are used.

2. Implant is atraumatically screwed in, as opposed to other implant systems which may require potentially damaging pounding in order to fully seat the implant.

3. Instrumentation can be used ALIF, PLIF, as well as laparoscopic implantation for anterior use (laparscopic approach could be anterior or anterolateral, depending on instrumentation used).

4. The instrumentation allows for simultaneous removal of the disc/bone and implant preparation. Three options are possible here: (1) drill/reamer to remove and contain disc and bone (no distractor present, except in contralateral side), (2) cannulated reamer for drilling over long distractor, and (3) trephine for coring out disc and the circular portions of endplate via drilling over a long distractor.

5. Specialized threadforms help resist unscrewing.

6. Bone ingrowth surface texturing acts to anchor the implant system. Hydroxyapatite coating could further enhance bone bonding and attachment to the implant surface. Dr. Michelson later mentioned that we will need to look at the various means of applying the coating. Plasma spraying may result in excessive temperatures, so alternative means (e.g., ion beam assisted deposition?) will need to be explored.

7. Greater surface area is achievable via predistraction method. This should result in reduced incidents of subsidence. Predistraction allows for a larger and more controlled working area.

8. Bilateral placement should allow for load bearing further peripherally on the stronger cortical bone along the vertebral body rim.

9. Iliac crest autograft bone is used. This cancellous autograft is highly osteogenic and should further encourage a strong fusion. Future use of active bone substitutes could be envisioned as those materials become available. This is placed within a bone press and injected into the implant prior to implantation. The compressive preloading is a key feature and advantage of the system.

II. Historical Outline of Use of Bone Dowels for Spinal Fusion

1. Cloward (1956) was the first to use a single central bone dowel for anterior cervical fusion.

2. Wilterberger (1957) used bilateral bone dowels for posterior lumbar interbody fusion.

3. Crock (1981) developed the use of bilateral bone dowels for anterior lumbar fusion.

All methods use relatively weak autograft or non-osteogenic allograft.

III. Basics of the Surgical Method

1. Protective tubular member is placed.

2. Distraction is achieved via insertion of the bullet-nosed, long distractor.

3. A outer sleeve (with engagement teeth) is placed in order to maintain distraction.

4. A diameter-reducing inner sleeve is placed.

5. A drill/reamer with drill stop is then used to remove disc and bone.

6. The threaded implant is inserted into this hole, engaging the bone.

Overall, this method protects against:

1. Vessel or soft tissue damage (the outer tube provides protection from contact with surrounding tissues),

2. Over penetration (the fixed drill stops prevent over penetration),

3. Debris in wound (the system closed debris is contained within inner sleeve),

4. Damage from power instruments (drill stops prevent over drilling),

5. Misalignment (various long distractors and individual distractors hold place during procedure),

6. Loss of distraction (Long & short distractors and outer sleeve maintain distraction),

7. Off-center or non-parallel drilling (co-axial use of instrumentation centered about initial placement and confirmation of placement of bullet-nosed distractors assures accurate placement, outer sleeve engaged in vertebral bodies prevents spreading as drills engage),

8. Penetration of soft tissues or blood vessels (Blunt tips on initial long distractor prevents such damage, drill stops prevent over drilling).

IV. Issues/Questions/Answers

1. Pre-distraction allows the full diameter implant to be inserted. This is in contrast to other methods. Without the pre-distraction method (key to Michelson) a significant portion of the forward end of the implant is needed for the purpose of separating opposing vertebrae. This can be clearly seen in the Spine Tech BAK implant where a significant lead-in, ramped portion is required, which significantly reduces the threaded portion available for load-bearing and engagement.

2. A sharp thread can be used for the Michelson technique due to pre-distraction and protection of surrounding tissues by use of the external outer sleeve distractor for maintenance of distraction.

3. I was unclear about the need for an initial discectomy prior to insertion of the intra-discal distractors. I was also unclear about the amount of disc that should be removed. According to Dr. Michelson, some select discectomy may be needed. This could be achieved via use of a simple curette for removing some small portion of disc prior to inserting the initial, bullet-nosed long distractors.

4. The sequential placement of bilateral long distractors are inserted in order to assess the ideal disc height. Once the proper distractor size is placed it is very clear that the disc has reached its ideal tension. As has been mentioned by other surgeons, there is a very clear stopping point at which the annulus is in maximum tension and the disc has been restored to its normal disc height. The surgeon will determine when a balanced distraction is achieved via either a tactile sensation of a tight fit of the distractor or via actual radiographic confirmation of the re-establishment of disc height.

   The surgeon may need to remove one of the short distractors on one side in order to increase disc height during balancing. The anti-expulsion teeth may resist, but instrumentation exists for removing these short distractors in order to place a larger distractor. An alternative procedure allows for the use of the long distractor only with the trephine used to drill over this long distractor. This is especially

important where lordosis may be achieved via the wedge-shaped long distractors that may be used to re-establish the trapezoidal shape of the disc anatomy during PLIF. The advantages of the short distractors center around the fact that they may be placed and maintain disc height and distraction while the surgeon works on the other side. They also allow surgeons to balance the disc space, which may be very important for example in the case of reducing a spondylolisthesis.

5. In many cases a tap is not necessary. One would normally not tap following bone and disc removal in Michelson's preferred method. This is due to the fact that if one were to tap prior to inserting the implant it would be possible to accidentally crossthread the tapped disc vertebral endplates. That is, the very sharp threads on the Michelson implant could initially bite into the vertebral body bone and establish their own thread path as they are inserted. Obviously, if such a disc space had been previously tapped and were crossthreaded the implant bone interface would be less than ideal. The implant is, therefore, essentially self-tapping and cuts very well into the cancellous vertebral body bone. The tap that is provided with the set does allow for ideal tapping in that it compresses the bone rather than actually cutting a trough through the bone and removing valuable bone cells. We will need to test the various alternatives as we proceed with this program to determine the need for tapping and advantages/disadvantages.

6. The ideal implant configuration features the following:

    1. The preferred material is titanium (commercially pure or titanium alloy),
    2. The implant would be porous coated or textured in order to improve implant anchorage,
    3. The implant would be coated with hyroxyapatite coating in order to enhance bone attachment , bone migration around and thru the implant innerspace,
    4. The implant is only approximately 1mm in wall thickness. This is strong enough for short-term load bearing while a fusion occurs and provides for a maximum amount of bone within the center of the implant, as well as optimized bone bridging and thru-growth into the implant.
    5. The thread form may be interrupted and self-locking if such additional means of resisting expulsion are needed,
    6. The implant thread form is self-tapping, and
    7. the implant should be pre-loaded with autograft bone which is compressed into the implant until it extrudes out of the pores of the implant.

LB/dg